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APPLICATION NO. 08/548,318	FILING DATE 04/09/97	EMERSON FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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ZEMAN, M

EXAMINER

1643

ART UNIT

PAPER NUMBER

02/24/98

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks



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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/840,316	04/11/97	EMERSON	S 2026-4255

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OFFICE OF TECHNOLOGY TRANSFER
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EXAMINER

ZEMAN, M

ART UNIT PAPER NUMBER

1815

5

DATE MAILED: 01/23/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 8/12/97

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-24 is/are pending in the application.

Of the above, claim(s) 5, 6 + 10-24 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of Reference Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

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DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-4, and 7-9, drawn to polynucleotides, vectors, and methods of making a recombinant protein using those vectors, classified in class 536, subclass 23.1.
 - II. Claims 5, 6, 17-20 and 24 drawn to polypeptides, classified in class 530, subclass 350.
 - III. Claims 10-16, drawn to methods of detecting antibodies and kits for use therefore, classified in class 435, subclass 7.1.
 - IV. Claims 21-23, drawn to antibodies, classified in class 530, subclass 388.1.
2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the polypeptides can be isolated from infected cells or made synthetically.
3. Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

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§ 806.05(h)). In the instant case the polypeptides can be used in methods of immunization, or for antibody purification.

4. Inventions II and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the antibodies can be generated by immunization with native, or non-recombinant proteins, or by immunization with whole virus.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

6. During a telephone conversation with Richard Bork on 10/29/97 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-4 and 7-9. Please note these groups are slightly different than those discussed. Affirmation of this election must be made by applicant in responding to this Office action. Claims 5, 6, and 10-24 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

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amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Claim Objections

8. Claim 7 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the latervative only. See MPEP § 608.01(n). This claim will be examined as reading "according to any one of claims 1-4" in the interests of compact prosecution.

Claim Rejections - 35 USC § 112

9. Claims 1-4 and 7-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "consisting essentially of" in reference to polynucleotides is vague and indefinite as it is not known what parameters of the polynucleotide can be changed. It is not clear if applicant intends other HEV sequences to be attached to either end of the recited sequence, or whether some nucleic acid substitutions are included, or if other unrelated sequences (fusion domains etc) are to be included.

The method of claim 8 does not recite a step in which the protein is collected or obtained.

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Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

11. Claims 1, 2, and 7-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Reyes.

Claims 1 and 2 are drawn to DNA molecules comprising a sequence encoding amino acids 112-578 or 112-607. Claim 7 is drawn to a vector comprising those polynucleotides, and claim 9 is drawn to a host cell comprising that vector. Claim 8 is drawn to a methods of recombinantly expressing a protein using a host cell transformed with the vector of claim 7.

Reyes (US Patent 5,686,239) discloses DNA molecules encoding ORF 2 of HEV, vectors comprising those sequences, host cells comprising those vectors, and methods of making those proteins.

12. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsarev.

Tsarev (Tsarev et al. 1992 PNAS USA 89:559-563) discloses DNA molecules comprising the sequences encoding the HEV ORF2 protein of a Pakistani strain.

13. Claims 1-4 and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsarev.

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Tsarev (Tsarev et al. 1993 J Infect Dis. 168:369-378) discloses DNA polynucleotides comprising a sequence encoding amino acids 112-607 of the HEV ORF2 protein, vectors comprising those sequences, host cells comprising those vectors, and methods of expressing the proteins.

14. Claims 1-3 and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by He et al..

He (He et al. 1993 J Clin Microbiol. 31: 2167-2173) discloses DNA molecules comprising the sequence encoding aa 112-607 of the HEV ORF2 protein, vectors comprising those sequences, host cells comprising those vectors and methods of expressing the proteins.

15. Claims 1, 2 and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Li et al.

Li (Li et al. 1994 J Clin Microbiol. 32 (9) 2060-2066) discloses DNA molecules comprising a sequence encoding a HEV ORF2 protein, vectors comprising those sequences, host cells comprising those vectors and methods of expressing the proteins.

16. Claims 1, 2 and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by He et al.

He (He et al. 1995 J Clin Microbiol 33 (12) 3308-3311) discloses DNA molecules comprising a sequence encoding for the ORF2 protein of HEV, vectors comprising those proteins, host cells comprising those vectors, and methods of expressing the proteins.

17. Claims 1, 2 and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Panda et al..

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Panda (Panda et al. 1995 J Clin Microbiol. 33 (10) 2653-2659) discloses DNA molecules comprising a sequence encoding a HEV ORF2 protein, vectors comprising those sequences, host cells comprising those vectors and methods of expressing the proteins.

18. Claims 1-4 and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 94/06913.

Tsarev (WO 94/06913) discloses DNA molecules comprising a sequence encoding a HEV ORF2 protein, vectors comprising those sequences, host cells comprising those vectors and methods of expressing the proteins.

19. Claims 1, 2, and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 95/08632.

Anderson et al. (WO 95/08632) discloses DNA molecules comprising a sequence encoding a HEV ORF2 protein, vectors comprising those sequences, host cells comprising those vectors and methods of expressing the proteins.

20. Claims 1, 2 and 7-9 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 96/12807.

Fuerst et al. (WO 96/12807) discloses DNA molecules comprising a sequence encoding a C-terminal portion of a HEV ORF2 protein, vectors comprising those sequences, host cells comprising those vectors and methods of expressing the proteins.

21. No claim is allowed.

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22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (703) 305-7133. The examiner can be reached between the hours of 8:00 am and 5:30 pm Monday through Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marian Knode, can be reached on (703) 308-4311.

The fax number for this Art Unit is (703) 305-7939.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



mkz
January 16, 1998

**MARIAN C. KNODE
SUPERVISORY PATENT EXAMINER
GROUP 1800**